V.T.

Office Action Summary

Application No.	Applicant(s)
08/892,190	Atul M. Mehta et al.
Examiner	**Group Art Unit**
Ray Henley	1205

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-31* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *1-27 and 29-31* is/are allowed.

☒ Claim(s) *28* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

CLAIMS 1-31 ARE PRESENTED FOR EXAMINATION

Claim Rejections - 35 USC § 112

Claim 28 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of those diseases specifically set forth at pages 1-2 of the present specification under the heading "Background of the Invention", does not reasonably provide enablement for "treating disease in a patient in need of treatment". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim since the claim encompasses the treatment of any and all diseases while (a) methylphenidate was known to be effective for only those disease states specified and (b) no drug known is capable of treating all disease states.

Allowable Subject Matter

Claims 1-27 and 29-31 are deemed allowable over the cited prior art since none teach or suggest the presently claimed delayed release dosage preparation containing methylphenidate, or an isomer thereof, as an effective agent.

In particular, while a sustained release tablet of methylphenidate was known, (PDR-"Ritalin SR"), this preparation is taught to provide for a continuous release of the active agent rather than the pulse dosing which would occur after ingestion of the presently claimed product.

Nothing in the PDR, or any of the other cited references, is seen that would have motivated the skilled artisan to alter the dosage form taught in the PDR so as to arrive at the presently claimed product.

Sackler et al. (U.S. Patent No. 5,672,360) and Eichel et al. (U.S. Patent No. 5,478,573) teach dosage forms for pharmaceutically active agents which are consistent with applicants' physical requirements. However, neither teach methylphenidate, or a class of agents to which it belongs and neither are seen to provide teachings that would have motivated the skilled artisan to employ as the active agent, drugs other than those taught therein. Accordingly, claims 1-27 and 29-31 are believed to define subject matter that is patentable over the cited art. The references cited and not mentioned above are included to show the general state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1200

Henley; rjh
December 22, 1997